

whom 10 were identified with PI. Symptoms ranged from none to abdominal pain, abdominal distention, cough and respiratory distress. Diagnosis was established by CT scan ( $n = 7$ ), plain film ( $n = 2$ ) or colonoscopy ( $n = 1$ ). Nine of 10 pts had ongoing GI graft versus host disease (GVHD) at diagnosis or a recent history of treatment for GI GVHD. Prior to 04/02, 2 pts underwent subtotal colectomy with ileostomy ( $n = 1$ ) and sigmoid colectomy with colostomy ( $n = 1$ ). One pt was managed with bowel rest and total parental nutrition (TPN) only. These 3 pts died 0.4, 1.1, and 3.9 years after PI diagnosis due to GI GVHD ( $n = 2$ ) and surgical complications after colostomy revision ( $n = 1$ ). Seven PI pts diagnosed after 09/06 were treated with GI rest, TPN and oral antibiotics (rifaximin, augmentin and metronidazole) to decrease anaerobic bowel flora. Median duration of antibiotic use was 47 days (range:26–136+), one pt was still on antibiotics as of last follow up on 10/3/08), median duration of TPN was 41 days (range:25–64) and median duration of GI rest was 23 days (range:3–34). On this regimen, all 7 patients had resolution of PI at a median time of 36 days (range:10–70). Of the 7 pts, 5 died due to GI GVHD ( $n = 3$ ), relapsed disease ( $n = 1$ ) or pre-existing diverticulitis ( $n = 1$ ) at 0.92, 0.46, 0.07, 0.15, and 1.3 years after PI diagnosis. PI pts treated with GI rest, TPN and oral antibiotics may have resolution of PI. In most cases it is a non-critical finding that does not represent true GI tract ischemia and/or GI tract perforation. Non-surgical management of PI with therapy directed against anaerobic bacteria may result in complete resolution.

### 313

#### USE OF PALIFERMIN IN ALLOGENEIC STEM CELL TRANSPLANTATION (SCT) FOR PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

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**Background:** Palifermin is a recombinant keratinocyte growth factor (KGF) approved to decrease the incidence and severity of mucositis in stem cell transplantation. Furthermore, effects on the KGF receptor may modulate and minimize acute GVHD. Studies utilizing palifermin have been conducted in autologous SCT; however, literature regarding use in allogeneic SCT is minimal.

**Methods:** We evaluated time to engraftment, incidence/duration of mucositis, and incidence of acute GVHD in 22 ALL patients (15 M/7 F) treated from 2004 to 2008 with 12 Gy TBI, etoposide 60 mg/kg, and unmanipulated cells. Seven patients received weekly rituximab at 375 mg/m<sup>2</sup> x 4 doses as part of a study. GVHD prophylaxis consisted of mini-dose methotrexate and tacrolimus. Anti-thymocyte-globulin was added to matched unrelated patients. Patients also received 3 daily doses of palifermin 60 mcg/kg preceding initiation of chemotherapy, and following stem cell infusion. Outcomes were compared to a historical control group of 19 ALL patients (12 M/7 F) treated with a TBI-based preparative regimen who did not receive palifermin.

**Results:** The median age in the palifermin arm was 36.5 years (19–51) versus 34 years (16–52) in the historical arm. Donor type was matched related or matched unrelated in 12 and 10 patients, respectively, in the palifermin arm versus 11 and 8 patients, respectively, in the historical arm. All patients in palifermin and historical control groups developed mucositis. The median duration of mucositis was 13 days (3–28) in the historical arm and 14 days (3–27) in the palifermin arm. Patient-controlled analgesia was used in 14 patients for a median of 13.5 days in the historical arm versus 17 patients for a median of 13 days in the palifermin arm. Median time to ANC  $\geq 0.5 \times 10^9/L$  was 15 days (12–26) for the palifermin arm versus 14 days (12–26) for the historical arm; median time to platelet count  $\geq 20 \times 10^9/L$  was 15 days (6–30) for the palifermin arm and 13 days (5–37) for the historical arm. The incidence of grades II–IV and III–IV acute GVHD were 18% ( $n = 4$ ) and 5% ( $n = 1$ ), respectively, in the palifermin arm versus 32% ( $n = 6$ ) and 11% ( $n = 2$ ), respectively, in the historical arm.

**Conclusions:** Palifermin use for allogeneic SCT is feasible with no impact on engraftment, and possibly reduction in acute GVHD. However, we failed to detect reduction of mucositis with palifermin use. Our observations are limited by the retrospective nature of the comparisons and small patient numbers.

### 314

#### FEASIBILITY OF ALLOGENEIC PERIPHERAL BLOOD STEM CELL TRANSPLANTATION (ALLO-SCT) FOLLOWING REDUCED INTENSITY CONDITIONING (RIC) IN HIV+ PATIENTS WITH HEMATOLOGICAL MALIGNANCIES

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The role of RIC Allo-SCT in HIV+ patients with hematological malignancies remains to be defined. We employed a uniform strategy of RIC consisting of fludarabine (30 mg/m<sup>2</sup>/day, days -7 to -3), busulfan (0.8 mg/kg/dose IV x 8 doses) with ( $n = 2$ ) or without ( $n = 1$ ) (6mg/kg) rabbit ATG in three HIV+ patients with hematological malignancies. Median patient age was 51 yrs (range 39–55 yrs). One patient each had AML, Burkitt's lymphoma and plasmablastic lymphoma. All patients were in CR2 at the time of transplantation. Median pre-transplant (preT) CD4 count was 339cells/uL (range 189–457cells/uL). 2 patients had undetectable HIV viral load preT, while it was 814copies/ml in the third patient. All patients had HCl-comorbidity index of  $\geq 3$ . Donors included sibling ( $n = 1$ ) or unrelated volunteers ( $n = 2$ ). GVHD prophylaxis consisted of micro-dose methotrexate and tacrolimus. HAART was not interrupted during or after transplantation. All patients engrafted promptly following transplantation. Only one patient developed transient stage III cutaneous acute GVHD. While one patient each developed extensive and limited chronic GVHD. At a median follow-up of 375 days (range 71–526 days) all patients are alive, with no evidence of disease relapse. Post-transplant HIV viral load remains undetectable in 2 patients. In the third patient mildly elevated HIV viral load (2000copies/ml) on day +252, promptly became undetectable with second line HAART. Similarly the CD4 count remained  $>200$ cell/uL at all measurements post-transplantation. Chimerism analysis showed 100% donor CD33+ chimerism at all time points (days 30, 90, 180 and +365) and median donor CD3+ chimerism of 90%, 84%, and 100% at days +30, +180 and +365. One patient developed CMV reactivation which responded to preemptive antiviral therapy. No patients developed any HIV related opportunistic infections. This case series provides critical preliminary evidence that RIC Allo-SCT with concurrent uninterrupted HAART is safe and feasible in HIV+ patients with malignant hematological disorders.

### 315

#### A SINGLE APHERESIS PROCEDURE IN THE DONOR MAY BE ENOUGH TO COMPLETE AN ALLOGRAFT USING THE "MEXICAN METHOD" OF NON-ABLATIVE ALLOGRAFTING

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We have analyzed the salient apheresis features of a group of 175 allogeneic peripheral blood stem cell transplants conducted in two institutions in a seven-year period. The grafts were conducted using the "Mexican" non-myeloablative conditioning regimen employing oral busulfan, iv cyclophosphamide and iv fludarabine. In all instances, the apheresis machine employed was the Baxter CS3000 Plus and donors were mobilized with filgrastim. The apheresis procedures were performed on days -4, -3, and -2, the endpoint of collection being 5 000 ml of blood / m<sup>2</sup> in each procedure. Three apheresis sessions were planned but the number was adjusted according to the cell yield. The final number of allografted CD34 cells ranged between 0.5 and 25.4  $\times 10^6/Kg$  of the recipient (median 5.2  $\times 10^6/Kg$ ). One to 3 apheresis procedures were needed to accomplish a product containing above 0.5  $\times 10^6/Kg$  of the recipient CD34 cells, the median being 2 procedures; in 72 cases (41%) a single apheresis procedure was enough to obtain the target number of CD34 cells. The apheresis products volumes ranged between 50 and 600 ml (median 400). Since the median cost of each apheresis procedure is 900 USD, the cost of two apheresis procedures was spared in 72 procedures, whereas the cost of one was spared in 65, thus making an approximate total amount of 188 100 USD saved. It is concluded that allogeneic transplants can be completed using a single apheresis session and that considerable economic consequences can be derived from this practice.